

**ALKA-SELTZER PLUS SEVERE COUGH MUCUS AND CONGESTION DAY AND NIGHT - acetaminophen, dextromethorphan hydrobromide, doxylamine succinate, phenylephrine hydrochloride, guaifenesin
Bayer HealthCare LLC.**

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Alka-Seltzer Plus® Severe Cough, Mucus & Congestion Day & Night Liquid Gels

Do not take these products at the same time.

Alka-Seltzer Plus® Severe Cough, Mucus & Congestion Day Liquid Gels

Drug Facts

Active ingredients (in each capsule)

Acetaminophen 250 mg

Dextromethorphan hydrobromide 10 mg

Guaifenesin 200 mg

Phenylephrine hydrochloride 5 mg

Purposes

Pain reliever/fever reducer

Cough suppressant

Expectorant

Nasal decongestant

Uses

- helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive
- temporarily relieves these symptoms due to a cold or flu:
- nasal congestion · sinus congestion and pressure
- minor aches and pains · headache
- cough · sore throat
- temporarily reduces fever

Warnings

Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take

- more than 4,000 mg of acetaminophen in 24 hours
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks every day while using this product

Allergy alert: Acetaminophen may cause severe skin or severe allergic reactions. Symptoms may include:

- skin reddening · blisters · rash · hives

· facial swelling · asthma (wheezing) · shock

If a skin or general allergic reaction occurs, stop use and seek medical help right away.

Sore throat warning: If sore throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache, rash, nausea, or vomiting, consult a doctor promptly.

Do not use

- with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.
- if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric, or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product.
- if you have ever had an allergic reaction to this product or any of its ingredients
- in children under 12 years of age

Ask a doctor before use if you have

- liver disease • heart disease • high blood pressure
- thyroid disease • diabetes
- difficulty in urination due to enlargement of the prostate gland
- persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis or emphysema
- cough with excessive phlegm (mucus)

Ask a doctor or pharmacist before use if you are taking the blood thinning drug warfarin

When using this product do not exceed recommended dosage

Stop use and ask a doctor if

- pain, cough, or nasal congestion gets worse or lasts more than 7 days
- fever gets worse or lasts more than 3 days
- redness or swelling is present
- new symptoms occur
- cough comes back or occurs with fever, rash or headache that lasts.

These could be signs of a serious condition.

- nervousness, dizziness, or sleeplessness occurs

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away. Quick medical attention is critical for adults as well as for children even if you do

not notice any signs or symptoms.

Directions

Directions

- do not take more than the recommended dose
- adults and children 12 years and over: take 2 capsules with water every 4 hours. Do not exceed 10 capsules in 24 hours or as directed by a doctor.
- children under 12 years: do not use

Other information

Other information

store at 15-25°C (59-77°F)

Inactive ingredients FD&C red #40, gelatin, glycerin, polyethylene glycol, povidone, propylene glycol, purified water, shellac, sodium hydroxide, sorbitol-sorbitan solution, titanium dioxide

Questions or comments?

Questions or comments? 1-800-986-0369 (Mon-Fri 9AM - 5PM EST)

Alka-Seltzer Plus® Severe Cough, Mucus & Congestion Night Liquid Gels

Drug Facts

Active ingredients (in each capsule)

Acetaminophen 325 mg

Dextromethorphan hydrobromide 10 mg

Doxylamine succinate 6.25 mg

Phenylephrine hydrochloride 5 mg

Purposes

Pain reliever/fever reducer

Cough suppressant

Antihistamine

Nasal decongestant

Uses

- temporarily relieves these symptoms due to a cold or flu:
- minor aches and pains · headache
- nasal and sinus congestion · cough
- sore throat · runny nose · sneezing
- temporarily reduces fever

Warnings

Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take

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- with other drugs containing acetaminophen
- 3 or more alcoholic drinks every day while using this product

Allergy alert: Acetaminophen may cause severe skin or severe allergic reactions. Symptoms may include:

- skin reddening · blisters · rash · hives
- facial swelling · asthma (wheezing) · shock

If a skin or general allergic reaction occurs, stop use and seek medical help right away.

Sore throat warning: If sore throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache, rash, nausea, or vomiting, consult a doctor promptly.

Do not use to sedate children.

Do not use

- with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.
- if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric, or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product.
- if you have ever had an allergic reaction to this product or any of its ingredients
- in children under 12 years of age

Ask a doctor before use if you have

- liver disease ● heart disease ● high blood pressure
- thyroid disease ● diabetes ● glaucoma
- cough with excessive phlegm (mucus)
- a breathing problem such as emphysema or chronic bronchitis
- difficulty in urination due to enlargement of the prostate gland
- persistent or chronic cough such as occurs with smoking, asthma, or emphysema

Ask a doctor or pharmacist before use if you are

- taking the blood thinning drug warfarin
- taking sedatives or tranquilizers

When using this product

- do not exceed recommended dosage
- may cause marked drowsiness
- avoid alcoholic drinks
- alcohol, sedatives, and tranquilizers may increase drowsiness
- be careful when driving a motor vehicle or operating machinery
- excitability may occur, especially in children

Stop use and ask a doctor if

- pain, cough, or nasal congestion gets worse or lasts more than 7 days
- fever gets worse or lasts more than 3 days
- redness or swelling is present
- new symptoms occur
- cough comes back or occurs with rash or headache that lasts.

These could be signs of a serious condition.

- nervousness, dizziness, or sleeplessness occurs

If pregnant or breast-feeding, ask a health professional before use.

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or contact a Poison Control Center right away. Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

Directions

- do not take more than the recommended dose
- adults and children 12 years and over: take 2 capsules with water every 4 hours. Do not exceed 10 capsules in 24 hours or as directed by a doctor.
- children under 12 years: do not use

Other information

- store at 15-25 C 59-77 F

Inactive ingredients FD&C blue #1, D&C yellow #10, gelatin, glycerin, polyethylene glycol, povidone, propylene glycol, purified water, shellac, sodium hydroxide, sorbitol sorbitan solution, titanium dioxide

Questions or comments? 1-800-986-0369 (Mon-Fri 9AM - 5PM EST)



Do not take these products at the same time.

**Alka-Seltzer Plus® Severe Cough,
Mucus & Congestion Day Liquid Gels**

Drug Facts

**Active ingredients
(in each capsule)**

Purposes

Acetaminophen 250 mg..... Pain reliever/fever reducer
 Dextromethorphan hydrobromide 10 mg..... Cough suppressant
 Guaifenesin 200 mg..... Expectorant
 Phenylephrine hydrochloride 5 mg..... Nasal decongestant

Uses

- helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive
- temporarily relieves these symptoms due to a cold or flu:
 - nasal congestion
 - sinus congestion and pressure
 - minor aches and pains
 - headache
 - cough
 - sore throat
- temporarily reduces fever

Warnings

Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take

**Alka-Seltzer Plus® Severe Cough,
Mucus & Congestion Night Liquid Gels**

Drug Facts

**Active ingredients
(in each capsule)**

Purposes

Acetaminophen 325 mg..... Pain reliever/fever reducer
 Dextromethorphan hydrobromide 10 mg..... Cough suppressant
 Doxylamine succinate 6.25 mg..... Antihistamine
 Phenylephrine hydrochloride 5 mg..... Nasal decongestant

Uses

- temporarily relieves these symptoms due to a cold or flu:
 - minor aches and pains
 - headache
 - nasal and sinus congestion
 - cough
 - sore throat
 - runny nose
 - sneezing
- temporarily reduces fever

Warnings

Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take

- more than 4,000 mg of acetaminophen in 24 hours
- with other drugs containing acetaminophen

- more than 4,000 mg of acetaminophen in 24 hours
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks every day while using this product

LIFT HERE

- 3 or more alcoholic drinks every day while using this product
- Allergy alert:** Acetaminophen may cause severe skin or severe allergic reactions. Symptoms may include:
- skin reddening
 - blisters
 - rash
 - hives
 - facial swelling
 - asthma (wheezing)
 - shock
- If a skin or general allergic reaction occurs, stop use and seek medical help right away.

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Alka-Seltzer Plus® Severe Cough, Mucus & Congestion Day Liquid Gels

Drug Facts (continued)

Allergy alert: Acetaminophen may cause severe skin or severe allergic reactions. Symptoms may include:

- skin reddening
- blisters
- rash
- hives
- facial swelling
- asthma (wheezing)
- shock

If a skin or general allergic reaction occurs, stop use and seek medical help right away.

Sore throat warning: If sore throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache, rash, nausea, or vomiting, consult a doctor promptly.

Do not use

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- if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric, or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product.
- if you have ever had an allergic reaction to this product or any of its ingredients
- in children under 12 years of age

Ask a doctor before use if you have

- liver disease
- heart disease
- high blood pressure
- thyroid disease
- diabetes
- difficulty in urination due to enlargement of the prostate gland
- persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis or emphysema
- cough with excessive phlegm (mucus)

Alka-Seltzer Plus® Severe Cough, Mucus & Congestion Night Liquid Gels

Drug Facts (continued)

Sore throat warning: If sore throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache, rash, nausea, or vomiting, consult a doctor promptly.

Do not use to sedate children.

Do not use

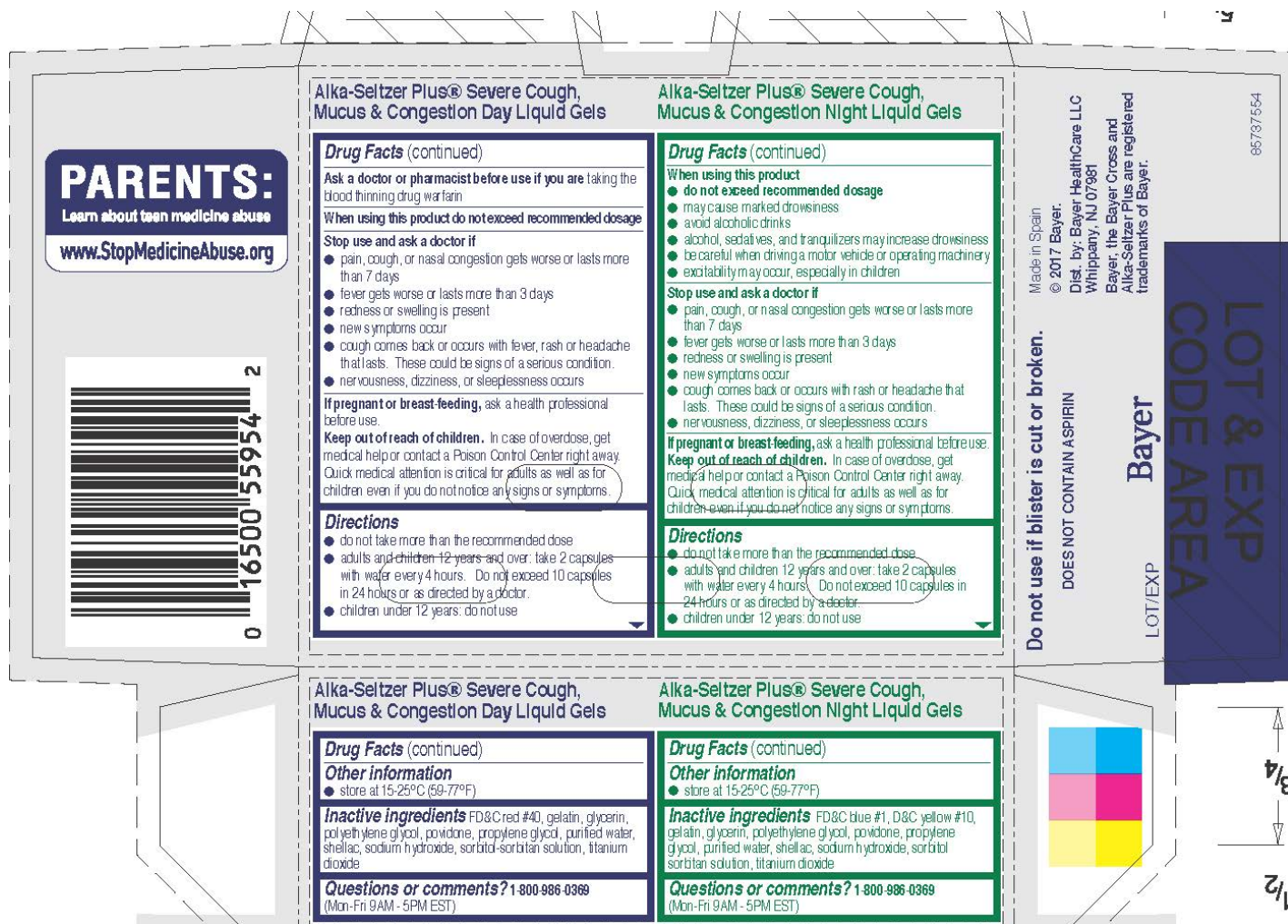
- with any other drug containing acetaminophen (prescription or non-prescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.
- if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric, or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product.
- if you have ever had an allergic reaction to this product or any of its ingredients
- in children under 12 years of age

Ask a doctor before use if you have

- liver disease
- heart disease
- high blood pressure
- thyroid disease
- diabetes
- glaucoma
- cough with excessive phlegm (mucus)
- a breathing problem such as emphysema or chronic bronchitis
- difficulty in urination due to enlargement of the prostate gland
- persistent or chronic cough such as occurs with smoking, asthma, or emphysema

Ask a doctor or pharmacist before use if you are

- taking the blood thinning drug warfarin
- taking sedatives or tranquilizers



ALKA-SELTZER PLUS SEVERE COUGH MUCUS AND CONGESTION DAY AND NIGHT

acetaminophen, dextromethorphan hydrobromide, doxylamine succinate, phenylephrine hydrochloride, guaifenesin kit

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0280-0506
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0280-0506-20	1 in 1 CARTON; Type 0: Not a Combination Product	05/30/2017	

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	2 BLISTER PACK	12
Part 2	2 BLISTER PACK	8

Part 1 of 2

ALKA-SELTZER PLUS SEVERE COUGH, MUCUS AND CONGESTION DAY

acetaminophen, dextromethorphan hydrobromide, phenylephrine hydrochloride, guaifenesin capsule, liquid filled

Product Information

Route of Administration ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	250 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	200 mg

Inactive Ingredients

Ingredient Name	Strength
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
WATER (UNII: 059QF0KO0R)	
SHELLAC (UNII: 46N107B71O)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
SORBITAN (UNII: 6O92ICV9RU)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GELATIN (UNII: 2G86QN327L)	
POVIDONE (UNII: FZ989GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SORBITOL (UNII: 506T60A25R)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	

Product Characteristics

Color	red	Score	no score
Shape	OVAL	Size	20mm
Flavor		Imprint Code	AS;M
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		2 in 1 CARTON		
1		6 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	06/12/2017	

Part 2 of 2

ALKA-SELTZER PLUS SEVERE COUGH MUCUS AND CONGESTION NIGHT
acetaminophen, dextromethorphan hydrobromide, doxylamine succinate, phenylephrine hydrochloride capsule,
liquid filled

Product Information

Route of Administration	ORAL
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Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DOXYLAMINE SUCCINATE (UNII: V9BI9B5YI2) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	6.25 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg

Inactive Ingredients

Ingredient Name	Strength
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
SORBITAN (UNII: 6O92ICV9RU)	
SORBITOL (UNII: 506T60A25R)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
GELATIN (UNII: 2G86QN327L)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0KO0R)	
SHELLAC (UNII: 46N107B71O)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
POVIDONE (UNII: FZ989GH94E)	

Product Characteristics

Color	green	Score	no score
Shape	OVAL	Size	20mm

Flavor		Imprint Code	AS;Nite	
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		2 in 1 CARTON		
1		4 in 1 BLISTER PACK; Type 0: Not a Combination Product		
Marketing Information				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final		part341	06/12/2017	
Marketing Information				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final		part341	05/30/2017	

Labeler - Bayer HealthCare LLC. (112117283)

Revised: 11/2019

Bayer HealthCare LLC.